

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO		<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		<i>Application Number</i>	10/612,603
		<i>Filing Date</i>	July 1, 2003
		<i>First Named Inventor</i>	Chappey et al.
		<i>Art Unit</i>	1648
		<i>Examiner Name</i>	Humphrey, L.
<i>(Use as many sheets as necessary)</i>		<i>Attorney Docket Number</i>	57618-386029
Sheet	1	of	4

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

⁶EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. "Applicant's unique citation designation number (optional)." See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).⁷ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.⁸ Applicant is to place a check mark here if English language translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete the form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

2

of

4

Complete if Known

Application Number	10/612,603
Filing Date	July 1, 2003
First Named Inventor	Chappey et al.
Art Unit	1648
Examiner Name	Humphrey, L.
Attorney Docket Number	57618-386029

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	5	ABRAVAYA, K. et al., "Detection of point mutations with a modified ligase chain reaction (Gap-LCR)," 1995, Nuc. Acids Res., 23:675-682
	6	ALLAIN, J.-P. et al., "Long-Term Evaluation of HIV Antigen and Antibodies to p24 and gp41 in Patients with Hemophilia," 1987, N. Engl. J. Med., 317:1114-1121
	7	ALTSCHUL, S. et al., "Basic Local Alignment Search Tool," 1990, J. Mol. Biol. 215:403-410
	8	ALTSCHUL, S. et al., "Gapped BLAST and PSI-BLAST: a new generation of protein database search programs," 1997, Nucleic Acids Res., 25:3389-3402
	9	BARANY, F. "Genetic disease detection and DNA amplification using cloned thermostable ligase," 1991, Proc. Natl. Acad. Sci. USA, 88:189-193
	10	BARRE-SINOUSSI, F. et al., "Isolation of a T-lymphotropic Retrovirus from a Patient at Risk for Acquired Immune Deficiency Syndrome (AIDS)," 1983, Science, 220:858-871
	11	COLONNO, R. et al., "Identification of 150L as the Signature Atazanavir (ATV)-Resistance Mutation in Treatment-Naive HIV-1-Infected Patients Receiving ATV-Containing Regimens," The Journal of Infectious Diseases, May 15, 2004; 189:1802-10
	12	COTTON, R. et al., "Reactivity of cytosine and thymine in single-base-pair mismatches with hydroxylamine and osmium tetroxide and its application to the study of mutations," 1968, Proc. Natl. Acad. Sci. USA, 65:4397-4401
	13	Current Protocols in Molecular Biology, Ausubel, F.M. et al. eds., John Wiley & Sons, NY, 2010 Table of Contents and list of yearly supplements
	14	FAHAM, M. and COX, D., "A Novel In Vivo Method to Detect DNA Sequence Variation," 1995, Genome Res., 5:474-482
	15	FISCHER, S. and LERMAN, L., "DNA fragments differing by single base-pair substitutions are separated in denaturing gradient gels: Correspondence with melting theory," 1983, Proc. Natl. Acad. Sci. USA, 80:1579-83
	16	FREEDMAN, D., PISANI, R., and PURVES, R., 1980, Statistics, W.W. Norton, New York
	17	GOEDERT, J. et al., "Effect to T4 Count and Cofactors on the Incidence of AIDS in Homosexual Men Infected With Human Immunodeficiency Virus," 1987, JAMA, 257:331-334
	18	GUPTA, S. et al., "Combinations of Mutations in the Connection Domain of Human Immunodeficiency Virus Type 1 Reverse Transcriptase: Assessing the Impact of Nucleoside and Nonnucleoside Reverse Transcriptase Inhibitor Resistance," May 2010, American Society for Microbiology, Vol. 54, No. 5, p. 1973-1980
	19	HIRSCH, M. et al., "Antiretroviral Drug Resistance Testing in Adult HIV-1 Infection: 2008 Recommendations of an International AIDS Society-USA Panel," July 15, 2008, Clinical Infectious Diseases, 47:266-85
	20	KAN, Y. and DOZY, A., "Antenatal Diagnosis of Sickle-Cell Anaemia by D.N.A. Analysis of Amniotic-Fluid Cells," 1987, The Lancet, 2:910-912

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

3

of

4

Complete if Known

Application Number	10/612,603
Filing Date	July 1, 2003
First Named Inventor	Chappay et al.
Art Unit	1648
Examiner Name	Humphrey, L.
Attorney Docket Number	57618-386029

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	21	KARLIN, S. and ALTSCHUL, S., "Methods for assessing the statistical significance of molecular sequence features by using general scoring schemes," 1990, Proc. Natl. Acad. Sci. USA, 87:2264-2268
	22	KARLIN, S. and ALTSCHUL, S., "Applications and statistics for multiple high-scoring segments in molecular sequences," 1993, Proc. Natl. Acad. Sci. USA, 90:5673-5677
	23	KELLAM, P. and LARDER, B., "Recombinant Virus Assay: a Rapid, Phenotypic Assay for Assessment of Drug Susceptibility of Human Immunodeficiency Virus Type 1 Isolates," 1994, Antimicrobial Agents and Chem., 38:23-30
	24	LANDEGREN, U. et al., "A Ligase-Mediated Gene Detection Technique," 1988, Science, 241:1077-1080
	25	LUCAS, S. "The pathology of HIV infection," 2002, Lepr. Rev., 73:64-71
	26	MAXAM, A. and GILBERT, W., "Sequencing End-Labeled DNA with Base-Specific Chemical Cleavages," 1980, Methods in Enzymology, 65:499-560
	27	MESSING, J. et al., "A system for shotgun DNA sequencing," 1981, Nuc. Acids Res., 9:309-321
	28	MYERS, R. et al., "Detection of Single Base Substitutions by Ribonuclease Cleavage at Mismatches in RNA:DNA Duplexes," 1985, Science, 230:1242-1246
	29	NIKIFOROV, T. et al., "Genetic Bit Analysis: a solid phase method for typing single nucleotide polymorphisms," 1994, Nuc. Acids Res., 22:4167-4175
	30	NORRIS, T., "HIV Update," 2002, Radiol. Technol., 73:339-363
	31	ORITA, M. et al., "Rapid and Sensitive Detection of Point Mutations and DNA Polymorphisms Using the Polymerase Chain Reaction," 1989, Genomics, 5:874-879
	32	ORITA, M. et al., "Detection of polymorphisms of human DNA by gel electrophoresis as single-strand conformation polymorphisms," 1989, Proc. Natl. Acad. Sci. USA, 86:2766-2770
	33	ORUM, H. et al., "Single base pair mutation analysis by PNA directed PCR clamping," 1993, Nuc. Acids Res., 21:5332-5336
	34	PCR Strategies, 1995, Innis et al. eds., Academic Press, Inc.
	35	PEARSON, W. and LIPMAN, D., "Improved tools for biological sequence comparison," 1988, Proc. Natl. Acad. Sci. USA, 85:2444-2448

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered, include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to provide a copy here of English language translation if translation is provided. This collection of information is required by 37 CFR 1.95. The information is required to obtain or retain a benefit in the public which is to file (or by the USPTO to process) an application. Confidentiality is guaranteed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for Form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT			
(Use as many sheets as necessary)			
Sheet	4	of	4
		Application Number	10/612,603
		Filing Date	July 1, 2003
		First Named Inventor	Chappey et al.
		Art Unit	1648
		Examiner Name	Humphrey, L.
		Attorney Docket Number	57618-386029

NON-PATENT LITERATURE DOCUMENTS

NON-PATENT LITERATURE DOCUMENTS		
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	36	PIATAK, M. et al., "High Levels of HIV-1 in Plasma During All Stages of Infection Determined by Competitive PCR," 1983, Science, 259:1749-1754
	37	POPCVIC, M. et al., "Detection, Isolation, and Continuous Production of cytopathic Retroviruses (HTLV-III) from Patients with AIDS and Pre-AIDS," 1984, Science, 224:497-500
	38	RICHMAN, D., "Resistance, Drug Failure, and Disease Progression," 1994, AIDS Research Hum. Retroviruses 10:901-905
	39	RUSSELL, W. et al., "Specific-locus test shows ethynitrosourea to be the most potent mutagen in the mouse," 1979, Proc. Natl. Acad. Sci. USA, 76:5818-5819
	40	SAMBROOK et al., 2001, Molecular Cloning : A Laboratory Manual, Cold Spring Harbor Laboratory, 3rd ed., NY
	41	SANGER, F. et al., "DNA sequencing with chain-terminating inhibitors," 1977, Proc. Natl. Acad. Sci USA, 74:5463-5467
	42	SOUTHERN, E.M., "Detection of Specific Sequences Among DNA Fragments Separated by Gel Electrophoresis," 1975, J. Mol. Biol., 98:503-517
	43	SYVANEN, C. et al., "A Primer-Guided Nucleotide Incorporation Assay in the Genotyping of Apolipoprotein E," 1990, Genomics, 8:584-592
	44	THIEDE, C. et al., "Simple and sensitive detection of mutations in the ras proto-oncogenes using PNA-mediated PCR clamping," 1996, Nucl. Acids Res., 24:983-984
	45	TORELLI, A. and ROBOTTI, C., "ADVANCED and ADAM: two algorithms for the analysis of global similarity between homologous informational sequences," 1994, Comput. Appl. Biosci., 10:3-5
	46	URDEA, M., "Synthesis and Characterization of Branched DNA (bdNA) for the Direct and Quantitative Detection of CNV, HBV, HCV, and HIV," 1993, Clin. Chem., 39:725-726
	47	WAGNER, R. et al., "Mutation detection using immobilized mismatch binding protein (MutS)," 1995, Nucl. Acids Res., 23:3944-3948
	48	WHITCOMB, J. et al., "Broad Nucleoside Reverse-Transcriptase Inhibitor Cross-Resistance in Human Immunodeficiency Virus Type 1 Clinical Isolates," 2003, J. Infectious Diseases, 188:992-1000
	49	YOUIL, R. et al., "Screening for mutations by enzyme mismatch cleavage with T4 endonuclease VII," 1995, Proc. Natl. Acad. Sci USA, 92:87-91

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is requested to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.